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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,856	03/26/2004	Osama Kandil	KAN-002-B	7581

31496 7590 06/01/2006

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EXAMINER

LEITH, PATRICIA A

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/809,856		KANDIL, OSAMA	
	Examiner		Art Unit	
	Patricia Leith		1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 6-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 20-22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>5/5/06</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-22 are pending in the application.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-5 and 20-22 in the reply filed on May 5, 2006 is acknowledged. The traversal is on the ground(s) that the different groups would not be a burden to search. Applicant notes that the Examiner has previously searched the methods and the compositions on the merits. This is not found persuasive because the previously searched invention did not include all of the methods as Instantly claimed. It is reiterated that if the product is found allowable, the methods will be rejoined for consideration on the merits if they conform to the requirements as set forth in the original restriction requirement.

The requirement is still deemed proper and is therefore made FINAL.

Claims 6-19 are hereby withdrawn from the merits as they are directed toward a non-elected invention.

Claims 1-5 and 20-22 were examined on their merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5 and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haresh et al. (1989).

Haresh et al. tested petroleum ether extracts from several plants including *N.sativa* on the hormone activity of *Dysdercus similis* (Table 3 and p.213). Thus, a 'lipid fraction' of *N.sativa* was known. Please note that although the reference did not specifically teach *N.sativa* L., *N.sativa* L. and *N.sativa* are the same species (the 'L.' is merely indicative of the 'Linn.' type of classification and does not further define the plant with regard to phenotypical and/or genotypical characteristics). Thus the *N.sativa* extract disclosed by Haresh et al. makes obvious the claimed invention.

It is deemed that the oil disclosed by Haresh et al. would have contained all of the fatty acids, glyceryl esters, volatile oils and sterols and would also be free of solid fats as Instantly claimed, especially lacking evidence to the contrary.

Haresh et al. did not specifically teach the incorporation of a pharmaceutical carrier, wherein the oil was incorporated into a lotion or spray for example, wherein the oil consisted essentially of polyunsaturated fatty acids, saturated fatty acids, glyceryl esters, volatile oils and sterols, wherein the oil was present in a composition in a particular ratio, or a particular ratio of volatile oils to sterols.

One of ordinary skill in the art would have been motivated to add a carrier such as an alcohol for spraying for example, or another oil in order to 1) dilute the *N.sativa* oil to varying concentrations and 2) to ease the dispersement of *N.sativa* oil to areas where insects reside.

It is well known in the art that two plants of the same species will rarely comprise the same exact endogenous phytochemical ratios. Haresh et al. clearly disclosed the oil of *Nigella sativa*. Thus, it is deemed that their oil was the same, or so similar to Applicant's *N. sativa* oil that no discernable differences can be made.

Claims 1-5 and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kandil (US 2002/0132019 A1).

It is clear that US 2002/0132019 A1 (Applicant's application published September 19, 2002) disclosed the oil fraction of *N. sativa* (see figures 1 and 2 for example).

The reference does not specifically teach wherein the composition was added to a pharmaceutical carrier.

Although the reference does not specifically teach any uses for the oil, it is clear that the oil was known. One of ordinary skill in the art would have been motivated to add a carrier to the oil in order to dilute the water for further laboratory testing.

It is suggested that Applicant perfect priority to application 10/029,886 in order to overcome this rejection. This will involve resurrecting application 10/029,886 (with a petition to revive) and petitioning to perfect the priority date of the Instant application while specifically stating how this application relates to '886 and an amendment to the Specification which includes this priority information. More information with regard to perfecting priority follows:

If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 120, a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an

application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that

Art Unit: 1655

the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Thursday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655

May 23, 2006

A handwritten signature in black ink, appearing to read 'Patricia Leith', with a large, stylized loop at the end.